

Environmental Protection Agency

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§ 158.243 Experimental use permit data requirements for terrestrial and aquatic nontarget organisms.

All terrestrial and aquatic nontarget organism data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. The indoor use pattern includes products

classified under the general use patterns of indoor food and indoor nonfood use.

(2) Data are also required for the general use patterns of forestry and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; commas between the test substances (e.g. TGAI, TEP) indicate that data may be required on the TGAI or TEP depending on the conditions set forth in the test note.

(c) *Table.* The following table shows the experimental use data requirements for terrestrial and aquatic nontarget organisms. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT TERRESTRIAL AND AQUATIC NONTARGET ORGANISM DATA REQUIREMENTS

Guideline No.	Data Requirement	Use Pattern						Test substance	Test Note No.
		Terrestrial	Aquatic	For-estry	Resi-dential Out-door	Green-house	Indoor		
Avian and Mammalian Testing									
850.2100	Avian oral toxicity	R	R	R	R	CR	CR	TGAI	1, 2, 3
850.2200	Avian dietary toxicity	R	R	R	R	NR	NR	TGAI	1, 4
Aquatic Organisms Testing									
850.1075	Freshwater fish toxicity	R	R	R	NR	NR	NR	TGAI, TEP	1, 2, 5, 6, 11
850.1010	Acute toxicity freshwater invertebrates	R	R	R	NR	NR	NR	TGAI, TEP	1, 2, 6, 7, 11
850.1300	Aquatic invertebrate life cycle (freshwater)	NR	R	R	NR	NR	NR	TGAI	1, 7, 8
850.1400	Fish early-life stage (freshwater)	NR	R	R	NR	NR	NR	TGAI	1, 8, 9
Accumulation Study									
850.1730	Fish	CR	CR	CR	NR	NR	NR	TGAI or PAIRA	10
Insect Pollinator Testing									
850.3020	Honeybee acute contact toxicity	R	R	R	NR	NR	NR	TGAI	1

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Data using the TGAI are required to support all outdoor end-use product uses including, but not limited to, turf. Data are generally not required to support end-use products in the form of a gas, a highly volatile

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liquid, a highly reactive solid, or a highly corrosive material.

2. For greenhouse and indoor end-use products, data using the TGAI are required to support manufacturing-use products to be reformulated into these same end-use products or to support end-use products when there is no registered manufacturing-use product. Avian acute oral data are not required for liquid formulations for greenhouse and indoor uses. The study is not required if there is no potential for environmental exposure.

3. Data are required on one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. Data are preferred on waterfowl or upland game bird species for indoor and greenhouse uses.

4. Data are required on waterfowl and upland game bird species.

5. Data are required on one coldwater fish and one warmwater fish for terrestrial, aquatic, forestry, and residential outdoor uses. For indoor and greenhouse uses, testing with only one of either fish species is required.

6. EP or TEP testing is required for any product which meets any of the following conditions:

i. The end-use pesticide will be introduced directly into an aquatic environment (e.g., aquatic herbicides and mosquito larvicides) when used as directed.

ii. The maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment is \geq one-half the LC_{50} or EC_{50} of the TGAI when the EP is used as directed.

iii. An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.

7. Data are required on one freshwater aquatic invertebrate species.

8. Data are generally not required for outdoor residential uses, other than turf, unless data indicate that pesticide residues from the proposed use(s) can potentially enter waterways.

9. Data are required on one freshwater fish species. If the test species is different from the two species used for the freshwater fish acute toxicity tests, a 96 hour LC_{50} on that species must also be provided.

10. Not required when:

i. The octanol/water partition coefficients of the pesticide and its major degradates are $<1,000$; or

ii. There are no potential exposures to fish and other nontarget aquatic organisms; or

iii. The hydrolytic half-life is <5 days at pH 5, 7 and 9.

11. The freshwater fish test species for the TEP testing is the most sensitive of the species tested with the TGAI. A freshwater invertebrate must also be tested with the EP or TEP using the same species tested with the TGAI.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.250 Experimental use permit data requirements for human exposure.

No data for applicator exposure and post-application exposure must be submitted to support a request for an experimental use permit.

§ 158.260 Experimental use permit data requirements for environmental fate.

All environmental fate data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *Use patterns.* (1) The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, and terrestrial nonfood. The aquatic use pattern includes the general use patterns of aquatic food crop, aquatic nonfood residential, and aquatic nonfood outdoors. The greenhouse use pattern includes both food and nonfood uses. The indoor use pattern includes food, nonfood, and residential indoor uses.

(2) Data are also required for the general use patterns of forestry use and residential outdoor use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; PAIRA=Pure active ingredient radio-labeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for environmental fate. The test notes are shown in paragraph (d) of this section.